IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MARCIA E. BRICE, Individually and on behalf all others similarly situated, Plaintiff, v. AMNEAL PHARMACEUTICALS, INC.,; -and- WALMART STORES, INC.,; -and- JOHN DOES 1-100, Defendants.	Civil Action No.:_____ **JURY TRIAL DEMANDED**

MEDICAL MONITORING CLASS ACTION COMPLAINT

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I. INTRODUCTION

1. Plaintiff brings this action on behalf of herself and all others who consumed Defendants' generic Metformin that was contaminated with an IARC- and EPA-listed probable human carcinogen known as N-nitrosodimethylamine ("NDMA"), in the United States, and who thus suffered cellular damage, genetic harm, and/or are at an increased risk of developing cancer as a result, but have not yet been diagnosed with cancer. Plaintiff seeks injunctive and monetary relief, including creation of a fund to finance independent medical monitoring services, including but not limited to notification to all people exposed to this contamination, examinations, testing, preventative screening, and care and treatment of cancer resulting, at least in part, from the exposure to the NDMA contamination.

2. At all times during the period alleged herein, Defendant represented and warranted to consumers that their generic Metformin containing drugs ("MCDs") were otherwise fit for their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

3. However, for years, Defendant willfully flouted federal current Good Manufacturing Practices ("cGMPs") and ignored other warnings signs that Defendants' MCDs contained or likely contained NDMA and/or other impurities.

4. Metformin is a first-line diabetes treatment and is often referred to as the "gold standard" of diabetes management, and has been generic for decades. Defendants' adulterated MCDs were illegally introduced into the American market for Defendant to profit from their sale to American consumers, such as Plaintiff and Class Members.

5. Plaintiff thus consumed Defendants' MCDs that were illegally introduced into the market by Defendants, exposing Plaintiff to highly dangerous and potentially fatal carcinogenic substances. Defendants' conduct requires medical monitoring and constitutes negligence, defective manufacture, failure to warn, a violation of the Magnuson-Moss Warranty Act, breach of implied warranty of merchantability, breach of express warranty, fraudulent concealment, and other legal violations as set forth herein.

II. PARTIES

6. Plaintiff Marcia E. Brice is a citizen and resident of the State of Florida, who resides and is domiciled in Port Charlotte, Florida. She was prescribed and used Defendants' product Metformin HCL 500mg ER from approximately 2018 to 2020. This MCD was contaminated with NDMA. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiff will develop cancer.

7. Defendant Amneal Pharmaceuticals, Inc. ("Amneal") is a Delaware corporation with its principal place of business at 400 Crossing Blvd., Bridgewater Township, NJ 08807. At all times material to this case, Amneal has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States.

8. Defendant Walmart Stores, Inc. ("Wal-Mart") is a Delaware corporation with its principal place of business in Bentonville, Arkansas. According to Defendant Wal-Mart's 2018 Form 10-K, Wal-Mart maintains approximately 4,769 retail locations in all fifty states nationwide and the District of Columbia and Puerto Rico (including supercenters, discount stores, and neighborhood markets and other small format locations). Most or all of these locations have Wal-Mart health and wellness products and services, which includes prescription pharmaceutical services. There are another approximately 600 Sam's Club locations across the United States, all or nearly all offering prescription pharmaceutical services. Defendant Wal-Mart (including Sam's Club) sold a large portion of the contaminated, adulterated, and/or misbranded MCDs to U.S. consumers across the country during the class period as defined below.

B. <u>True Names / John Doe Defendants 1-50</u>

9. The true names, affiliations, and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of John Does 1

through 50 are unknown to Plaintiff at this time. Plaintiff therefore sues these defendants using fictitious names. Each John Doe proximately caused damages to Plaintiff as alleged below, and each John Doe is liable to Plaintiff for the acts and omissions alleged below as well as the resulting damages. Plaintiff will amend this Complaint to allege the true names and capacities of the John Does when evidence reveals their identities.

10. At all times relevant to this Complaint, each of the John Does was the agent, servant, employee, affiliate, and/or joint venturer of the other co-defendants and other John Does. Moreover, each Defendant and each John Doe acted in the full course, scope, and authority of that agency, service, employment, and/or joint venture.

III. JURISDICTION AND VENUE

11. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendants, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.

12. This Court has personal jurisdiction over Defendants pursuant to 28 U.S.C. § 1407, and because Defendants have sufficient minimum contacts in

New Jersey, and because Defendants have otherwise intentionally availed themselves of the markets within New Jersey through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

13. Venue is proper in this District because all Defendants are residents of the State in which this District is located, 28 U.S.C. § 1391(b)(1); "a substantial part of the events or omissions giving rise to the claim occurred" in this District, 28 U.S.C. § 1391(b)(2); and Defendants are subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

IV. FACTUAL ALLEGATIONS

A. Metformin Background

14. Metformin is an oral antihyperglycemic drug used as a first-line therapy in the treatment and management of type 2 diabetes. It is often referred to as the "gold standard" of diabetes management because it is well-tolerated and cost-effective.

15. Metformin was first discovered in 1922, and first marketed in the United States in 1995. Metformin is regarded as so critical to diabetes management that it is listed by the WHO on the WHO's List of Essential Medicines.

16. In 2016, Metformin was the fourth-most prescribed medicine in the United States, with more than 81 million prescriptions dispensed.

17. Metformin is sold in many forms, though the original formulation lost patent exclusivity in September 2000.

B. Generic Drugs Must Be Chemically the Same as Branded Drug Equivalents

18. According to the FDA, "[a] generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that **a generic medicine works in the same way and provides the same clinical benefit as its brand-name version.** In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."[1]

19. While brand-name medications undergo a more rigorous review before being approved, generic manufacturers are permitted to submit an ANDA, which only requires a generic manufacturer to demonstrate that the generic medicine is the same as the brand name version in the following ways:

a. The active ingredient(s) in the generic medicine is/are the same as in the brand-name drug/innovator drug.

[1] FDA, GENERIC DRUGS: QUESTIONS & ANSWERS, https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last visited August 7, 2020) (emphasis in original).

b. The generic medicine has the same strength, use indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical).

c. The inactive ingredients of the generic medicine are acceptable.

d. The generic medicine is manufactured under the same strict standards as the brand-name medicine.

e. The container in which the medicine will be shipped and sold is appropriate, and the label is the same as the brand-name medicine's label.[2]

20. The drugs ingested by Plaintiffs were approved by the FDA, based upon Defendants' representations that they met the above criteria.

21. ANDA applications do not require drug manufacturers to repeat animal studies or clinical research on ingredients or dosage forms already approved for safety and effectiveness.[3]

22. Further, because generic drugs are supposed to be nearly identical to their brand-name counterparts, they are also supposed to have the same risks and benefits.[4]

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[2] FDA, GENERIC DRUG FACTS, https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm167991.htm (last visited August 7, 2020).

[3] FDA, GENERIC DRUGS: QUESTIONS & ANSWERS, https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last visited August 7, 2020).

[4] *Id.*

C. Misbranded and Adulterated or Misbranded Drugs

23. The manufacture of any adulterated or misbranded drug is prohibited under federal law.[5]

24. The introduction into commerce of any misbranded or adulterated or misbranded drug is similarly prohibited.[6]

25. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.[7]

26. Among the ways a drug may be adulterated and/or misbranded are:

a. "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;"[8]

b. "if … the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice…as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;"[9]

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[5] 21 U.S.C. § 331(g).
[6] 21 U.S.C. § 331(a).
[7] 21 U.S.C. § 331(c).
[8] 21 U.S.C. § 351(a)(2)(A).
[9] 21 U.S.C. § 351(a)(2)(B).

c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and … its quality or purity falls below, the standard set forth in such compendium. …"[10]

d. "If … any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[11]

27. A drug is misbranded:

a. "If its labeling is false or misleading in any particular."[12]

b. "If any word, statement, or other information required…to appear on the label or labeling is not prominently placed thereon…in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[13]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient…"[14]

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of

[10] 21 U.S.C. § 351(b).
[11] 21 U.S.C. § 351(d).
[12] 21 U.S.C. § 352(a)(1).
[13] 21 U.S.C. § 352(c).
[14] 21 U.S.C. § 352(e)(1)(A)(ii)

administration or application, in such manner and form, as are necessary for the protection of users. …"[15]

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein."[16]

f. "if it is an imitation of another drug;"[17]

g. "if it is offered for sale under the name of another drug."[18]

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[19]

i. If the drug is advertised incorrectly in any manner;[20] or

j. If the drug's "packaging or labeling is in violation of an applicable regulation…"[21]

28. As articulated in this Complaint, Defendant's unapproved drug was adulterated and/or misbranded as a result of contamination with NDMA, which was not approved, and was not disclosed.

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[15] 21 U.S.C. § 352(f).
[16] 21 U.S.C. § 352(g).
[17] 21 U.S.C. § 352(i)(2).
[18] 21 U.S.C. § 352(i)(3).
[19] 21 U.S.C. § 352(j).
[20] 21 U.S.C. § 352(n).
[21] 21 U.S.C. § 352(p).

D. The Drug Ingested by Plaintiff Was Not Metformin, But a New, Unapproved MCD

29. The FDA's website provides the definition for a drug:

> The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA regulations define the term drug, in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated by FDA as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients.[22]

30. 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."

[22] FDA, HUMAN DRUGS, https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug (last visited August 7, 2020).

31. NDMA causes cellular and genetic injury triggering genetic mutations in humans that can ultimately develop into cancer. These injuries affect the structure of the human body, and thus, NDMA is, by definition, an active ingredient in a drug.

32. FDA further requires that whenever a new active ingredient is added to a drug, the drug becomes an entirely new drug, necessitating a submission of a New Drug Application by the manufacturer. Absent such an application, followed by a review and approval by the FDA, this new drug remains a distinct, unapproved product.[23]

33. This new and unapproved drug with additional active ingredients (such as a nitrosamine in the subject MCD) cannot be required to have the same label as the brand-name drug, as the two products are no longer the same.

34. At the very least and alternatively, drugs contaminated with different and dangerous ingredients than their brand-name counterparts are adulterated or misbranded under federal law, and the sale or introduction into commerce of adulterated or misbranded drugs is illegal.[24]

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[23] *See* 21 C.F.R. § 310.3(h).

[24] *See generally* Department of Justice, *Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA* (May 13, 2013), https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false.

35. Because the MCD ingested by Plaintiff was never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs. Further, if such an assessment were performed, the drugs would not have been approved with the NDMA contamination.

36. The inclusion of an additional active ingredient (NDMA), and potentially other deviations from Defendant's ANDA approvals rendered Defendant's MCD unapproved, adulterated, misbranded drugs that are distinct from the FDA-approved generic Metformin.

37. Plaintiff references federal law in this Complaint not in any attempt to enforce it, but to demonstrate that her state-law tort claims do not impose any additional obligations on Defendant, beyond what is already required of it under federal law.

E. Defendant Made False Statements in the Labeling of its MCD

38. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[25] and conform to requirements governing the appearance of the label.[26]

[25] 21 C.F.R. § 201.5.
[26] 21 C.F.R. § 801.15.

39. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[27] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

40. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[28]

41. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[29]

42. In addition, by referring to its drug as "Metformin HCL 500mg ER" Defendants were making false statements regarding their MCD.

43. Because NDMA was not disclosed by Defendants as an ingredient in the MCD ingested by Plaintiff, the Defendants failed to warn consumers and physicians of the true ingredients, and the subject drugs were misbranded.

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[27] *Id*.; 65 Fed. Reg. 14286 (March 16, 2000).
[28] *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).
[29] 21 C.F.R. § 201.6; 201.10.

44. It is unlawful to introduce a misbranded drug into interstate commerce.[30] Thus, the MCD ingested by Plaintiff was unlawfully distributed and sold.

F. The Generic Drug Supply Chain in the United States

45. The generic drug supply chain from manufacturer to end consumer involves several groups of actors and links.

46. At the top of the supply chain are generic drug manufacturers (and whomever they contract with to manufacture components of pharmaceuticals including, for example, the active pharmaceutical ingredient manufacturer ("API")). Generic drug manufacturers may sell to other manufacturers or to so-called repackagers or labelers who sell a particular generic drug formulation.

47. Wholesalers in turn purchase bulk generic drug product from the generic manufacturers and/or labelers and repackager entities. The wholesaler market is extremely concentrated, with three entities holding about 92% of the wholesaler market: Cardinal Health, Inc.; McKesson Corporation; and Amerisource Bergen Corporation.

48. Wholesalers sell the generic drug products they acquire to retail pharmacies, who sell them to patients with prescriptions in need of fulfillment. The retail pharmacy market is also dominated by several major players.

[30] 21 U.S.C. § 331(a).

G. The Generic Drug Approval Framework

49. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

50. The stated purpose of Hatch-Waxman is to strike a balance between rewarding genuine innovation and drug discovery by affording longer periods of brand drug marketing exclusivity while at the same time encouraging generic patent challenges and streamlining generic drug competition so that consumers gain the benefit of generic drugs at lower prices as quickly as possible.

51. Brand drug companies submitting a New Drug Application ("NDA") are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

52. By contrast, generic drug companies submit an ANDA. Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

1. ANDA Applications Must Demonstrate Bioequivalence

53. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two

drug products is evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

54. As part of its showing of bioequivalence pursuant to 21 C.F.R. § 314.50(d), the ANDA must also contain specific information establishing the drug's stability, including:

> a full description of the drug's substance, including its physical and chemical characteristics and stability; and
>
> the specifications necessary to ensure the identify strength, quality and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability.

55. Generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement

of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C).

56. A generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

2. ANDA Applications Must Provide Information About the Manufacturing Plants and Processes

57. The ANDA application must also include information about the manufacturing facilities of the product, including the name and full address of the facilities, contact information for an agent of the facilities, and the function and responsibility of the facilities.

58. The ANDA application must include a description of the manufacturing process and facility and the manufacturing process flow chart showing that there are adequate controls to ensure the reliability of the process.

59. Furthermore, the ANDA application must contain information pertaining to the manufacturing facility's validation process, which ensures that the manufacturing process produces a dosage that meets product specifications.

3. ANDA Applications Must Comply with cGMPs

60. Additionally, ANDA applications must include certain representations pertaining to compliance with cGMPs.

61. The ANDA application is required to contain cGMP certifications for both the ANDA applicant itself, and also and the drug product manufacturer (if they are different entities).

4. ANDA Approval is Contingent upon Continuing Compliance with ANDA Representations of Sameness

62. Upon granting final approval for a generic drug, the FDA will typically state that the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD[31] branded drug. Pharmacists, physicians, and patients can expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the same labeling as the RLD delivered to consumers in each prescription of its generic products. Further, by simply marketing generic drugs pursuant to the brand-name drug's label under the generic name (e.g., Metformin or Metformin HCT), generic manufacturers warrant that the generic drug is therapeutically equivalent to the brand-name drug.

[31] The FDA's Drug Glossary defines an RLD as follows: "A Reference Listed Drug (RLD) is an approved drug product to which new generic versions are compared to show that they are bioequivalent. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New Drug Application (ANDA). By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart."

63. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new and unapproved drug.

64. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, the generic manufacturer may no longer rely on the brand-name drug's labeling.

65. According to the FDA, there are more than twenty (20) ANDAs approved for Metformin.

H. Background on Current Good Manufacturing Practices ("cGMPs")

66. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

67. 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it

purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

68. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

69. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

70. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j).

Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors' operations.

71. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

72. There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

73. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

74. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug

product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

75. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

I. The Valisure Citizen Petition

76. Valisure is an online pharmacy licensed in thirty eight (38) states and also an analytical laboratory accredited by the International Organization for Standardization ("ISO"). Valisure is registered with the Drug Enforcement Administration (Pharmacy: FV7431137, Laboratory: RV0484814) and FDA (FEI #: 3012063246). Valisure has also maintained voluntary registration status with the FDA.

77. Valisure states that "its mission is to help ensure the safety, quality and consistency of medications and supplements in the market."

78. On or about March 2, 2020, Valisure submitted a Citizen Petition ("the CP") to the FDA regarding its findings of high levels of contamination of

various generic metformin products with an IARC- and EPA-listed probable human carcinogen known as NDMA.

79. Valisure's CP states that "the presence of NDMA in metformin products may be primarily due to contamination during manufacturing as opposed to a fundamental instability of the drug molecule[.]"

80. Specifically with regard to generic Metformin products manufactured by Amneal, Valisure's testing (which closely followed the FDA own analytical methods) revealed NDMA contamination levels of between 395 and 450 ng/tablet, with levels reaching up to 16.5x the FDA's interim daily limit in Amneal's Metformin ER products.

81. Although the FDA has consistently stated that no levels of NDMA should be present in prescription drugs, it has set an interim safety limit of 96 ng/day purely out of drug shortage fears if all such products were recalled

J. Amneal's cGMP Failures

82. As notes in the Valisure CP, "the presence of NDMA in metformin products may be primarily due to contamination during manufacturing." Amneal has been the subject of extensive FDA investigations revealing its seriously flawed and unreliable manufacturing practices and a history of recurring and ongoing cGMP violations.

83. Amneal's problematic manufacturing practices were first noted by the FDA as early as 2003, when the FDA cited Amneal because "[t]he assay method of testing stability samples has not been shown to be stability-indicating that the firm has not demonstrated peak purity for the active peak."

84. This inspection would only be the first of such damning inspections conducted by the FDA from 2003 to present. In fact, Amneal's facilities were inspected an astounding 94 times in this time period.

85. During one of these most recent inspections in April 2018 of Amneal's Indian manufacturing facilities, Amneal was cited for not reviewing, or even requesting to review, raw data from testing outsourced by Amneal to third-party vendors.

86. Concomitantly to this inspection in India, Amneal's Piscataway, NJ manufacturing facility was also inspected by the FDA, and the FDA found that Amneal failed to appropriately maintain or create written records of investigations into unexplained discrepancies.

87. During a February 2019 inspection, Amneal's Branchburg, NJ manufacturing facility was cited for failure to thoroughly review unexplained discrepancies, and failures of batches to meet set specifications, as well as failure to test all materials provided by component suppliers to validate the information provided by the suppliers.

K. Background on NDMA

88. N-nitrosodimethylamine, commonly known as NDMA, is an odorless, yellow liquid.[32]

89. According to the U.S. Environmental Protection Agency ("EPA"), "NDMA is a semi-volatile chemical that forms in both industrial and natural processes."[33]

90. NDMA can be unintentionally produced in and released from industrial sources through chemical reactions involving other chemicals called alkylamines.

91. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[34]

92. The US Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.[35] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by

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[32] U.S. Public Health Service, *Toxicological Profile For N-Nitrosodimethylamine* (Dec. 1989), https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

[33] EPA, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17508.pdf.

[34] *Id.*

[35] *Id.*

several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[36]

93. Exposure to NDMA can occur through ingestion of food, water, or medication containing nitrosamines.[37]

94. Exposure to high levels of NDMA has been linked to liver damage in humans.[38]

95. According to the Agency for Toxic Substances and Disease Registry, "NDMA is very harmful to the liver of humans and animals. People who were intentionally poisoned on one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding."[39]

96. Other studies showed an increase in other types of cancers, including but not limited to stomach, colorectal, intestinal, kidney, liver, and other digestive tract cancers.

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[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] U.S. Public Health Service, *Toxicological Profile For N-Nitrosodimethylamine* (Dec. 1989), https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

97. The Environmental Protection Agency classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."[40]

98. The World Health Organization's ("WHO") International Agency for Research on Cancer ("IARC") classifies NDMA as one of sixty-six agents that are "probably carcinogenic to humans" (Classification 2A).

99. Anecdotally, NDMA has also been used in intentional poisonings.[41]

100. Most Assuredly, NDMA is not an FDA-approved ingredient for generic Metformin. Defendant's MCD does not identify NDMA as an ingredient on the product's label nor elsewhere.

101. The contaminated MCD consumed by Plaintiff and manufactured, labeled, marketed, distributed, and/or sold by Defendant was not therapeutically equivalent to its RLD, and was not manufactured in compliance with cGMPs.

102. Defendant illegally sold a contaminated, adulterated MCD to Plaintiff.

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[40] EPA, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17508.pdf.

[41] *See Chase Purdy, A common blood-pressure medicine is being recalled because of a toxic ingredient*, QUARTZ (July 18, 2018), https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/.

103. As a result of the consumption of NDMA, Plaintiff has been harmed, including, but not limited to, suffering cellular and genetic injury which creates and/or increases the risk that Plaintiff will develop cancer.

104. Medical monitoring of Plaintiff's conditions is necessary and required because of the nature of cancer, including the need for diagnosis and treatment as early as possible.

105. In the absence of medical monitoring to diagnose and treat cancer as early as possible, Plaintiff and other Class Members are at an increased risk of suffering from the development and progression of cancer, with delayed diagnosis significantly increasing the risk of harm and death.

106. If Defendant Amneal had not routinely disregarded the FDA's cGMPs, including those discussed throughout this Complaint, and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendant Amneal would have identified the presence of these nitrosamine contaminants almost immediately.

107. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of

significant phases or after storage for long periods.

21 C.F.R. § 211.110(c).

108. And as shown above, Defendant Amneal's own quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by each API manufacturer. If these sampling-related and quality-control-related cGMPs were properly observed by Defendant Amneal, the nitrosamine contamination in Defendant Amneal's MCD would have been discovered almost as soon as the contamination commenced. Defendants were thus on (at minimum) constructive notice that their MCD was adulterated from that point forward.

L. Defendant Amneal's Warranties and Fraudulent and Deceptive Statements to Consumers Regarding its Generic MCD

109. The Defendant Amneal made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about its contaminated, adulterated, and/or misbranded MCD.

110. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book.[42] The Orange Book is a public document; Defendant sought and received the

[42] FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) SHORT DESCRIPTION, https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm (last visited June 5, 2019).

inclusion of its Metformin product in the Orange Book upon approval of its ANDA. In securing FDA approval to market its generic MCD in the United States as an Orange Book-listed drug, Defendant was required to demonstrate that its generic MCD was bioequivalent to branded MCD.

111. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book, therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.

112. By introducing its Metformin products into the United States market under the name "Metformin" as a therapeutic equivalent to branded MCDs and with the FDA- approved label that is the same as that of branded MCDs, Defendant Amneal represented and warranted to end users that its products were in fact the same as and are therapeutically interchangeable with branded MCD.

113. In addition, Defendant Amneal affirmatively misrepresented and warranted to consumers through its websites, brochures, and other marketing or informational materials that its MCD complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

114. The presence of nitrosamines in Defendant Amneal's MCDs: (1) renders Defendant Amneal's MCDs non-bioequivalent (*i.e.*, not the same) to

the branded MCDs and thus non-therapeutically interchangeable with them, thus breaching Defendant Amneal's express warranties of sameness; (2) was the result of gross deviations from cGMPs rendering Defendant Amneal's MCDs non-therapeutically equivalent to the branded MCDs, thus breaching Defendant Amneal's express warranties of sameness; and (3) results in Defendant Amneal's MCDs containing an ingredient that is not also contained in the branded MCDs, also breaching Defendant Amneal's express warranty of sameness (and express warranty that the products contained the ingredients listed on each Defendant's FDA-approved label). Defendant Amneal willfully, recklessly, or negligently failed to ensure its MCD's label and other advertising or marketing statements accurately conveyed information about its product.

115. The presence of a nitrosamine in Defendant Amneal's MCD and Defendant Amneal's serial and willful failures to comply with cGMPs and other shortcomings in Defendant Amneal's generic drug manufacturing processes have resulted in Defendant Amneal's MCDs being misbranded and adulterated compared to Defendant's representations and warranties.

116. At all relevant times, Defendant Amneal has also impliedly warranted that its MCD was merchantable and fit for their ordinary purposes.

117. Naturally, due to its status as probable human carcinogen as listed by both the IARC and the U.S. EPA, NDMA is not an FDA-approved ingredient in

MCDs. The presence of NDMA and other similar nitrosamines or impurities in Defendant Amneal's MCDs means that Defendant has violated implied warranties to Plaintiffs and Class Members. The presence of NDMA in Defendant Amneal's MCDs results in Defendant Amneal's MCDs being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of their RLDs), breaching Defendant Amneal's implied warranty of merchantability and/or fitness for ordinary purposes.

118. For these and other reasons, Defendant Amneal's MCDs are therefore adulterated, misbranded, and/or unapproved, and it was illegal for Defendants' to have introduced such MCDs in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

119. Adulterated, misbranded, and/or unapproved MCDs contaminated with cancer-causing compounds are essentially worthless. No consumer (including Plaintiffs) would purchase (or reimburse for) these nitrosamine-laden MCDs. In fact, an adulterated, misbranded, and/or unapproved MCD cannot even be legally sold or purchased within the United States. This is especially so given that alternative, actual MCDs or competing medications with the same approved indications were available from other manufacturers. At a minimum, adulterated, misbranded and/or unapproved MCDs do not possess the same safety and efficacy

profile as their branded equivalents. As such, the contaminated MCDs were not what they were supposed to be.

120. Moreover, every consumer who purchased and ingested a contaminated MCD has been exposed to a nitrosamine, a carcinogenic agent with mutagenic properties that operates at the cellular and sub-cellular levels, that caused cellular and genetic injury creating and/or increasing the risk that Plaintiffs will develop cancer.

121. Retail pharmacies, like Wal-Mart, are where consumers purchase and fill prescriptions for pharmaceuticals. As a result, retail pharmacies and consumers have direct privity of contract. Thus, with each sale of prescription drugs, Wal-Mart impliedly warrants to consumers that the prescription drugs being sold to them are merchantable and/or fit for its ordinary uses.

122. By selling pharmaceutical prescription drugs in the stream of commerce, Wal-Mart warrants that the generic drugs for which they receive payments are the same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics. More generally, Wal-Mart warrants that prescription drugs they sell are of a standard quality.

123. Further, Wal-Mart is obligated under the Drug Supply Chain Security Act and common law to quarantine and investigate potentially illegitimate

(including contaminated, adulterated, and/or misbranded) drugs, and/or to exercise proper care in the dispensement of prescription drugs.

M. John Do Wholesaler and Dispensing Entities

124. Defendants John Doe 1-100 constitute one or more additional pharmacies and/or wholesalers that distributed adulterated, misbranded, and/or unapproved MCDs that were and/or capacities of John Doe Pharmacies and Wholesalers are not presently known. However, each John Doe proximately caused damages to Plaintiff and class members as alleged below, and each John Doe is liable to Plaintiffs for the acts and omissions alleged below as well as the resulting damages. Plaintiffs will amend this Complaint when evidence from discovery reveals their identities.

125. Each Wholesaler John Doe Defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs. Wholesaler Defendants knew or should have known, based on information provided or available from each manufacturer defendant, of the actual or potential adulteration, misbranding, or contamination of metformin they purchased from manufacturer defendants. Wholesaler Defendants expressly or impliedly warranted metformin they sold were not adulterated, misbranded, or contaminated, when in fact that was not the case.

N. Fraudulent Concealment and Tolling

126. Plaintiffs' and Class Members' causes of action accrued, at the earliest, on the date the Valisure CP was filed, or has not even accrued yet legally.

127. Alternatively, any statute of limitation or prescriptive period is equitably tolled on account of fraudulent concealment. Defendants each affirmatively concealed from Plaintiffs and other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge of their and other Defendants' cGMP violations with respect to Metformin, and of the fact that their Metformin products were adulterated and/or misbranded and contaminated with nitrosamines, and were not the same as branded MCDs.

128. For instance, no Defendant revealed to the public that their MCDs contained nitrosamines or was otherwise contaminated, adulterated, misbranded, and/or unapproved, or non-therapeutically equivalent to branded MCDs.

129. To the contrary, each Defendant continued to represent and warrant that their generic MCDs were the same as and therapeutically interchangeable with their branded MCDs by their failure to recall them.

130. Because of this, Plaintiffs and other Class Members did not discover, nor could they have discovered through reasonable and ordinarily diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations, lulled Plaintiffs

and Class Members into believing that the purchase and use of their MCDs were appropriate for what they believed to be non-adulterated or misbranded drugs despite their exercise of reasonable and ordinary diligence.

131. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiffs and other Class Members has been tolled. Plaintiffs and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiffs were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

V. PLAINTIFF MARCIA E. BRICE'S INDIVIDUAL FACTS

132. Plaintiff Marcia E. Brice is a citizen and resident of Port Charlotte, Florida.

133. The following table represents information for Plaintiff's purchases of Defendants' Metformin products:

Date	NDC	Manufacturer	Medication	Quantity
01/15/18	53746 0178 01	Amneal	HCL 500 MG ER	60
02/12/18	53746 0178 01	Amneal	HCL 500 MG ER	60
03/13/18	53746 0178 01	Amneal	HCL 500 MG ER	60
04/16/18	53746 0178 01	Amneal	HCL 500 MG ER	60
05/14/18	53746 0178 01	Amneal	HCL 500 MG ER	60
06/10/18	53746 0178 01	Amneal	HCL 500 MG ER	60

07/11/18	53746 0178 01	Amneal	HCL 500 MG ER	60
08/08/18	53746 0178 01	Amneal	HCL 500 MG ER	60
09/06/18	53746 0178 01	Amneal	HCL 500 MG ER	60
10/12/18	53746 0178 01	Amneal	HCL 500 MG ER	60
11/08/18	53746 0178 01	Amneal	HCL 500 MG ER	60
12/10/18	53746 0178 01	Amneal	HCL 500 MG ER	60
01/08/18	53746 0178 01	Amneal	HCL 500 MG ER	60
02/07/19	53746 0178 01	Amneal	HCL 500 MG ER	180
05/07/19	53746 0178 01	Amneal	HCL 500 MG ER	180
08/05/19	53746 0178 01	Amneal	HCL 500 MG ER	180
01/17/20	65162 0178 10	Amneal	HCL 500 MG ER	180
03/25/20	65162 0178 10	Amneal	HCL 500 MG ER	180
05/28/20	65162 0178 10	Amneal	HCL 500 MG ER	90

134. Plaintiff paid some or all of the purchase price for many of his metformin prescriptions and/or refills listed above, as well as others potentially.

135. The generic Metformin purchased by Plaintiff manufactured or sold by Defendants was not therapeutically equivalent to branded MCDs, was manufactured out of compliance with cGMPs, and was adulterated by its contamination with NDMA.

136. Defendants' generic Metformin was sold illegally to Plaintiff.

VI. CLASS ACTION ALLEGATIONS

137. Plaintiff brings this action on behalf of herself and, under Federal Rule of Civil Procedure 23(a), (b)(2), (b)(3), and (c)(4), as representatives of the classes defined as follows:

138. All individuals residing in the United States of America and its territories and possessions who consumed generic metformin-containing drugs

contaminated with NDMA (and/or other nitrosamines), manufactured by or for Defendants and marketed in the United States and its territories and possessions, at least since January 1, 1995, the "Nationwide Class."

139. In the alternative, Plaintiff alleges sub-classes for all individuals in each State, territory, or possession (including specifically Florida) who consumed generic metformin-containing drugs contaminated with NDMA (and/or other nitrosamines), manufactured by or for Defendants and marketed in the United States and its territories and possessions, at least since January 1, 1995. Collectively, the foregoing Nationwide Class and alternative state sub-class are referred to as the "Class."

140. Excluded from the Class, and from the other additional and alternative classes defined below, are Defendants and their subsidiaries and affiliates; all persons who make a timely election to be excluded from the Class or classes to the extent any class is an opt-out class or a hybrid opt-out class; governmental entities; and any judicial officers who preside over this case and their immediate family members. Also excluded from the Class are those consumers of MCDs who have been diagnosed with cancers as a result of taking Defendants' NDMA-contaminated MCDs.

141. Plaintiff reserves the right to narrow or expand the foregoing class definition, or create subclasses, in light of future fact discovery, and including as

the Court deems necessary. These may include, by way of example, bellwether classes or state or other sub-classes.

A. The Classes Meet the Rule 23 Requirements

386. Plaintiff meets the prerequisites of Rule 23(a), (b), and (c) to bring this action on behalf of the Class and Classes.

387. **Numerosity (Rule 23 (a)(1))**: While the exact number of Class Members cannot be determined without discovery, they are believed to consist of potentially millions of Metformin consumers nationwide. The Class Members are therefore so numerous that joinder of all members is impracticable.

388. **Commonality (Rule 23(a)(2))**: Even a single common question can drive a litigation and warrant certification. Here, material common questions of law and fact exist as to all Class Members, including but not limited to:

a. Whether each Defendant's MCDs were contaminated with NDMA and thus contaminated, adulterated, and/or misbranded;

b. Whether Defendants violated cGMPs regarding the manufacture of their MCDs;

c. Whether Defendants negligently or defectively manufactured the MCDs consumed by Plaintiff and other Class Members;

d. Whether Defendants misrepresented facts or failed to warn as to the contamination;

e. Whether each Defendant made and breached express or implied warranties of "sameness" to Plaintiff and other Class Members regarding their generic MCDs, representing they were the same as their RLDs;

f. Whether each Defendant affirmatively misrepresented that its MCDS were the same as branded MCDs and thus therapeutically interchangeable, or omitted the fact that it was not;

g. Whether each Defendant affirmatively misrepresented that it was compliant with cGMPs, or omitted the fact that it was not;

h. Whether Plaintiff and other Class Members have suffered cellular and/or genetic injury and are at increased risk of developing cancer as a result of each Defendant's unlawful conduct;

i. Whether testing is available for the cancers to which Plaintiff and the Class Members are at increased risk;

j. The nature and extent of medical monitoring, testing, examinations, and treatment necessary to address the risks created by Plaintiffs and other Class Members' consumption of MCDs contaminated with NDMA or NDEA;

k. When Plaintiff and other Class Members' claims for relief accrued;

l. Whether Defendants fraudulently concealed Plaintiff's and other Class Members' causes of action.

389. **Typicality (Rule 23(a)(3))**: Plaintiff's claims are typical of Class Members' claims. Plaintiff and other Class Members all suffered the same type of harm, including exposure to NDMA, cellular and/or genetic injury, cancer, and/or an increased risk of developing cancer, but have not yet been diagnosed with cancer. Plaintiff brings claims under the same legal and remedial theories as the class. Plaintiff's claims arise out of the same set of facts and conduct as all other Class Members.

390. **Adequacy of Representation (Rule 23(a)(4) and Rule(g))**: Plaintiff is committed to pursuing this action and have retained competent counsel experienced in pharmaceutical and products liability litigation, medical monitoring, consumer litigation, and class actions. Accordingly, Plaintiff and her counsel will fairly and adequately protect the interests of Class Members. Plaintiff's claims are coincident with, and not antagonistic to, those of the other Class Members and Plaintiff will fairly and adequately represent the interests of Class Members

391. **Rule 23(b)(2):** Defendants have acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Classes as a whole.

392. **Rule 23(b)(3) Predominance and Superiority:** Here, the common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and a class action is the superior method for fair and efficient adjudication of the controversy. The likelihood that individual Class Members will prosecute separate actions for medical monitoring is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues is furthermore not efficient, timely or proper. Judicial resources will be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated plaintiffs. Plaintiffs' counsel, highly experienced in pharmaceutical and product liability litigation, consumer litigation, class actions, and federal court litigation, foresee the efficient management of this case as a class action.

393. **Rule 23(c)(4) Issues Class:** To the extent the Court determines there are material differences in the relevant laws and that such differences present class manageability issues precluding nationwide class certification for all purposes, Plaintiff submits that a nationwide issue class is appropriate for determination of common material fact issues in the case, and are predicates for the entitlement to

medical monitoring (such as exposure, contamination, misconduct, increased risk, existence of testing and benefit of testing, among others).

VII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

NEGLIGENCE
(Individually and on Behalf of the Class)

394. Plaintiff repeats and re-alleges the preceding paragraphs as if fully set forth herein.

395. Each Defendant owed a duty to Plaintiff and the Classes to use and exercise reasonable and due care in the manufacturing, testing, distribution, labeling, marketing, warnings, disclosures, and sale of its MCDs.

396. Each Defendant owed a duty to Plaintiff and the Classes to ensure that the MCDs it sold in the United States were not contaminated with NDMA, contained only the ingredients stated in the label, were therapeutically equivalent to brand Metformin, and/or complied with cGMPs, and/or was not contaminated or adulterated.

397. Each Defendant owed a duty of care to Plaintiff and the Classes because they were the foreseeable, reasonable, and probable users of MCDs. Each Defendant knew, or should have known, that its Metformin product was contaminated with NDMA, did not contain only the ingredients stated, was not therapeutically equivalent to brand Metformin and/or did not comply with cGMPs,

and/or were adulterated, and each was in the best position to uncover and remedy these shortcomings.

398. Defendants negligently manufactured the Metformin at issue, causing contamination with NDMA, which is carcinogens.

399. Each Defendant failed to fulfill its duty of care. Each Defendant inadequately conducted or oversaw the manufacture, testing, labeling, distribution, marketing, warnings, disclosures, and sale of the Metformin at issue. Each Defendant knew that the aforesaid wrongdoing would damage Plaintiff and other Class Members.

400. Each Defendant negligently failed to promptly and immediately warn and disclose to Plaintiff and other Class Members, and the medical and regulatory communities, of the potential and actual contamination with NDMA as soon as it was discovered, delaying notice of this harmful and potentially fatal toxic exposure to a carcinogen and thus causing continued exposure to the carcinogenic contamination, and delaying necessary testing, examinations, surveillance, and treatment.

401. Defendants' negligent conduct created and then exacerbated an unreasonable, dangerous condition for Plaintiff and other Class Members.

402. Defendants acted with recklessness and willful and wanton disregard for the health of Plaintiff and other Class Members.

403. Each Defendant's own unreasonable, negligent actions and inactions were taken or not taken with willful and wanton disregard for the health of Plaintiff and other Class Members and created a foreseeable risk of harm to Plaintiff and other Class Members.

404. As a direct and proximate result of each Defendants' negligent conduct, Plaintiff and other Class Members have suffered cellular and genetic injury that creates and/or increases the risk that Plaintiffs will develop cancer, necessitating notice to all Class Members, sufficient funding for the tests and evaluations of each Class Member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

405. Plaintiff and Class Members seek compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment,

(4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

SECOND CLAIM FOR RELIEF

NEGLIGENCE PER SE
(Individually and on Behalf of the Class)

406. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

407. Each Defendant owed a duty to Plaintiff and the Class to use and exercise reasonable and due care in the manufacturing of its MCDs.

408. Each Defendant owed a duty to Plaintiff and the Class to ensure that the MCDs it sold in the United States were therapeutically equivalent to brand Metformin and complied with cGMPs and were not adulterated or misbranded.

409. Each Defendant owed a duty to Plaintiff and the Class because each state, territory, and possession has adopted /or adheres to federal cGMP and adulteration standards.

410. Each Defendant failed to comply with federal cGMPs and federal adulteration standards.

411. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class.

412. As a direct and proximate result of each Defendants' negligent conduct, Plaintiff and other Class Members have suffered cellular and genetic

injury which creates and/or increases the risk that Plaintiff will develop cancer, necessitating notice to all Class Members, sufficient funding for the tests and evaluations of each Class Member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

413. Plaintiff and Class Members seek compensatory damages for, and the creation of a fund to adequately finance the costs of, the creation of a fund to adequately finance the costs of medical monitoring procedures (1) to notify and alert all people exposed to NDMA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

THIRD CLAIM FOR RELIEF

MEDICAL MONITORING
(Individually and on Behalf of the Class)

414. Plaintiff repeats and re-alleges the preceding paragraphs as if fully set forth herein.

415. As a proximate result of Defendants' acts and omissions, the Class is at an increased risk of developing cancer above the normal base-level risk.

416. As alleged above, Defendant's Metformin product was contaminated with NDMA, an agent known to cause cancer in humans.

417. The Class Members may not develop cancer for many years.

418. The Class Members are at an increased risk as they consumed and/or ingested Defendants' MCDs for extended periods of time, some as many as several years, and as a result were exposed to a contaminant.

419. Upon information and belief, and based upon the internal and external investigations now made public, the Class is at an increased risk as they were exposed to NDMA and/or other nitrosamines.

420. NDMA is a hazardous, life-threatening, toxic substance that is known to cause cancer in humans.

421. The Class Members are at an increased risk of cancer as they were exposed to, consumed, and/or ingested Defendants' MCDs in quantities, and over periods of time sufficient to establish an exposure level that is considered to be hazardous to health, and that is considered to be sufficient to cause cancer or increase the risk of developing cancer.

422. The exposure was caused solely and proximately by Defendants' failure to adequately manufacture their MCDs to be therapeutically equivalent to

brand Metformin; their failure to address discrepancies in batches/doses of Metformin during quality control testing; their material misrepresentations, false statements, and other deceptive practices in continuing to claim that their Metformin product was safe for consumption and/or ingestion and therapeutically equivalent to Diovan.

423. Defendants had a duty to the Class Members to: ensure and warrant that their Metformin product was indeed therapeutically equivalent to brand Metformin as claimed and advertised to the Class Members; to disclose to the Class Members any defect, contamination, impurity or other potential health hazard known or discoverable by Defendants; and to ensure that their Metformin product was not safe, reliable, and non-hazardous for human consumption—its intended purpose.

424. As alleged above, Defendants' own negligent acts and omissions resulted in cancer, or an increased risk of developing cancer for all members of the Class. Cancer is a serious disease-causing life-threatening illness and debilitating cellular, genetic, and physical injury. Technology, analytical tools, test and/or monitoring procedures exist and are readily available to provide for the testing and early detection of cancer in patients. These technologies, tools tests and/or monitoring procedures are accepted and widely used by the scientific and medical community. These existing scientific methods include, but are not limited to,

guaiac-based fecal occult blood test (gFOBT), fecal immunochemical test (FIT), FIT-DNA test, Flexible Sigmoidoscopy, Colonoscopy, and CT Colonography (Virtual Colonoscopy).

425. Early detection of cancer in patients is one of the best, and sometimes the only means to treat cancer such that it does not cause lasting, permanent injury, illness, or death.

426. Early detection of cancer in patients necessarily allows patients to avail themselves of myriad forms of treatment, each of which is capable to altering the course of the illness, such as bringing the cancer into remission, removal of any malignant tumors, and other treatment to alleviate injury.

427. The tests and treatments for the early detection and treatment of cancer must be prescribed by a qualified physician, and are conducted according to the latest, contemporary, and widely accepted scientific principles. Because NDMA-associated cancer screenings may not be conducted with the frequency necessary to identify cancer in the absence of exposure to NDMA, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Plaintiff and Class Members require more frequent screenings not within the purview of routine medical exams.

428. The facts alleged above are sufficient or more than sufficient to plead a claim for medical monitoring as a cause of action.

429. Plaintiff seeks, on behalf of herself and the Class Members whom she seeks to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

FOURTH CLAIM FOR RELIEF

PRODUCTS LIABILITY-MANUFACTURING DEFECT (Individually and on Behalf of the Class)

430. Plaintiff repeats and re-alleges the preceding paragraphs as is fully set forth herein.

431. The Metformin at issue was defectively manufactured, as the manufacturing process caused contamination of the Metformin with NDMA.

432. Metformin contaminated with NDMA is by definition defectively manufactured.

433. Defendants' conduct in defectively manufacturing Metformin was reckless and taken with wanton and willful disregard for the health of Plaintiff and other Class Members.

434. Defendants are strictly liable for the harm caused by or contributed to by the defectively manufactured Metformin.

435. As a direct and proximate result, Plaintiff and other Class Members have been injured and suffered damages, in that Defendants' MCDs they consumed were contaminated with NDMA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

436. Plaintiff seeks, on behalf of herself and the Class Members, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical

and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

FIFTH CLAIM FOR RELIEF

FAILURE TO WARN
(Individually and on Behalf of the Class)

437. Plaintiff repeats and re-alleges the preceding paragraphs as is fully set forth herein.

438. Defendants failed to warn Plaintiff and the Class Members, and the medical and regulatory communities, of the potential or actual contamination of the Metformin with NDMA, as soon as this was suspected or known.

439. Defendants' failure to warn was intentional, reckless, and in wanton and willful disregard for the rights and health of Plaintiff and other Class Members, causing exposure to carcinogens and delay of diagnosis and treatment.

440. Defendants are strictly liable for their failure to warn or adequately disclose information.

441. As a direct and proximate result of each Defendant's failure to warn or disclose information, Plaintiff and other Class Members have been injured and suffered damages, in that Defendants' MCDs they consumed were contaminated with NDMA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

442. Plaintiff seeks, on behalf of herself and the Class Members, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

SIXTH CLAIM FOR RELIEF

VIOLATION OF THE MAGNUSSON-MOSS WARRANTY ACT 15 U.S.C. § 2301 *et seq.* (Individually and on Behalf of the Class)

443. Plaintiff repeats and re-alleges the preceding paragraphs as is fully set forth herein.

444. Plaintiff brings this Count on behalf of members of the Classes.

445. This Court has jurisdiction to decide claims brought under 15 U.S.C. § 2301 by virtue of 28 U.S.C. § 1332 (a)-(d).

446. The contaminated doses of Metformin are "consumer products" within the meaning of the Magnusson-Moss Warranty Act, 15 U.S.C. § 2301(1).

447. Plaintiff is a "consumer[]" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(3). She is a consumer because she is a person entitled under applicable state law to enforce against the warrantor the obligations of its express and implied warranties.

448. Defendants were "supplier[s]" and "warrantor[s]" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(4)-(5).

449. 15 U.S.C. § 2310(d)(1) provides a cause of action for any consumer who is damaged by the failure of a warrantor to comply with a written or implied warranty.

450. Defendants provided Plaintiff and the other Class members with an implied warranty of merchantability in connection with the purchase of Metformin that is an "implied warranty" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(7). As a part of the implied warranty of merchantability, Defendants warranted that the Metformin ultimately found to be contaminated with NDMA was fit for its ordinary purpose as a safe pharmaceutical medication, would pass without objection in the trade as designed, manufactured, and marketed, and were adequately contained, packaged, and labeled. N.J. Stat. Ann. § 12A:2-314(2)(a), (c), and (e); U.C.C. § 2-314.

451. Defendants breached these implied warranties, as described in more detail above, and are therefore liable to Plaintiff and the Class pursuant to 15 U.S.C. § 2310(d)(1). Without limitation, doses and/or batches of contaminated Metformin share common design defects in that they have caused cellular and/or genetic injury, cancer, or an increased risk of developing cancer.

452. In their capacity as warrantors, Defendants had knowledge of the defects in the batches of Metformin they manufactured, distributed, and sold, any efforts to limit the implied warranties in a manner that would exclude coverage of contaminated Metformin is unconscionable, and any such effort to disclaim, or otherwise limit, liability for contaminated Metformin is null and void.

453. Privity is not required here because Plaintiff and each of the other Class members are intended third-party beneficiaries of any contracts between Defendants and their distributors, and specifically, of the implied warranties. The distributors were not intended to be the ultimate consumers of Metformin and have no rights under the warranty agreements provided with each container of Metformin; the warranty agreements were designed for and intended to benefit consumers. Finally, privity is also not required because the contaminated batches and/or doses of Metformin are dangerous instrumentalities due to the aforementioned defects and nonconformities. In the alternative, to the extent it is required, it is satisfied.

454. Pursuant to 15 U.S.C. § 2310(e), Plaintiff is entitled to bring this class action and are not required to give Defendants notice and an opportunity to cure until such time as the Court determines the representative capacity of Plaintiffs pursuant to Rule 23 of the Federal Rules of Civil Procedure.

455. Furthermore, affording Defendants an opportunity to cure their breach of written warranties would be unnecessary and futile here. At the time of sale of each batch and/or dose of contaminated Metformin Defendants knew, should have known, or were reckless in not knowing of their misrepresentations concerning Metformin's contamination and failure to perform as warranted, but nonetheless failed to rectify the situation and/or disclose the contamination.

456. Plaintiff seeks injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment,

attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

SEVENTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY (Individually and on Behalf of the Class)

457. Plaintiff repeats and re-alleges the preceding paragraphs as if fully set forth herein.

458. Defendants are merchants with respect to Metformin within the laws of each jurisdiction.

459. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann.

§ 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841*, et seq.*; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

460. Each Defendant was a merchant within the meaning of the above statutes.

461. Each Defendants' Metformin product constituted "goods" or the equivalent within the meaning of the above statutes.

462. Each Defendant was obligated to provide Plaintiffs and other Class Members reasonably fit MCDs for the purpose for which the products were sold, and to conform to the standards of the trade in which Defendants are involved such that the products were not contaminated with a carcinogen and were of fit and merchantable quality.

463. Each Defendant knew or should have known that its MCDs were being manufactured and sold for the intended purpose of human consumption as a

therapeutic equivalent to brand Metformin (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that their MCDs were of merchantable quality and fit for that purpose.

464. Each Defendant breached its implied warranty because each Defendant's MCDs were contaminated with a carcinogen and not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

465. Defendants were provided notice of these issues by numerous discrepancies in quality control testing results, evidence of contaminants in analyses of batches/doses of Metformin, investigations conducted internally and by the FDA and communications sent by the Class before or within a reasonable amount of time after Defendants

466. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendants' MCDs they consumed were contaminated with NDMA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

467. Plaintiff seeks injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA or

contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

EIGHTH CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTIES
(Individually and on Behalf of the Class)

468. Plaintiff repeats and re-alleges the preceding paragraphs as if fully set forth herein.

469. Each Defendant expressly warranted that its MCDs were fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically to and interchangeable with brand Metformin. In other words, Defendants expressly warranted that their products were the same as brand Metformin.

470. Each Defendant sold MCDs that they expressly warranted were compliant with cGMP and/or not adulterated and/or misbranded.

471. Each Defendant's MCDs did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and/or was adulterated and/or misbranded.

472. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann.

§ 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

473. At the time that each Defendant marketed and sold its MCDs, it recognized the purposes for which the products would be used, and expressly warranted the products were the same as brand Metformin, and cGMP compliant and/or not adulterated and/or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiff and other Class Members, including but not limited to express representations made in referring to their MCDs as Metformin, Metformin HCT, amlodipine-Metformin, and and/or amlodipine-Metformin HCT.

474. Each Defendant breached its express warranties with respect to its MCDs as it was contaminated and not of merchantable quality, was not fit for its ordinary purpose, and did not comply with cGMP and/or was adulterated and/or misbranded.

475. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that the Defendants' MCDs they consumed were

contaminated with NDMA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

476. Plaintiff seeks injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA or contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

NINTH CLAIM FOR RELIEF

FRAUD/FRAUDULENT CONCEALMENT
(Individually and on Behalf of the Class)

477. Plaintiff repeats and re-alleges the preceding paragraphs as is fully set forth herein.

478. This claim is brought on behalf of the Nationwide Class or, alternatively, under the laws of the all states, as there is no material difference in

the law of fraud and fraudulent concealment as applied to the claims and questions in this case.

479. Defendants each concealed and suppressed material facts concerning the batches/doses of Metformin they manufactured, distributed, and sold, that were later found to be contaminated with NDMA.

480. As described above, Defendants each made material omissions and affirmative misrepresentations regarding the batches/doses of Metformin they manufactured, distributed, and sold.

481. The Defendants each knew these representations were false when made.

482. Metformin purchased by Plaintiff was, in fact, contaminated, hazardous, a health hazard, unsafe and unreliable, because the Metformin manufactured by Defendants had not been properly manufactured nor properly tested for quality, and was later found to be contaminated with known carcinogen NDMA.

483. The Defendants each had a duty to disclose that the Metformin they manufactured, distributed, and sold, had been contaminated with NDMA, had demonstrated such contamination and other analytical discrepancies when it underwent quality control, and that consequent to that contamination, those batches/doses of Metformin were potentially hazardous to the Class Members'

health and was unsafe for human consumption or ingestion. Plaintiff relied on Defendants' representations that the Metformin they were purchasing and ingesting was safe and free from contamination.

484. The aforementioned concealment was material, because if it had been disclosed Plaintiff would not have purchased or otherwise obtained Metformin from Defendants.

485. The aforementioned representations were also material because they were facts that would typically be relied on by a person purchasing or obtaining Metformin. The Defendants each knew or recklessly disregarded that their representations were false because they knew that the Metformin they were manufacturing, distributing, and selling was contaminated with NDMA, a substance known to cause cancer and/or increase the risk of cancer. The Defendants each intentionally made the false statements in order to sell Metformin and avoid the expense and public relations nightmare of a recall.

486. Plaintiff relied on the Defendants' reputation, along with their failure to disclose the contamination of Metformin and manufacturing and quality control problems, and the Defendants' affirmative assurances that their Metformin was safe for human consumption and/or ingestion.

487. However, Defendants each concealed and suppressed material facts concerning obligations to monitor and test their products.

488. Further, Defendants each had a duty to disclose the true facts about the contaminated Metformin because they were known and/or accessible only to Defendants who had superior knowledge and access to the facts, and the facts were not known to or reasonably discoverable by Plaintiff and the Classes.

489. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendants' MCDs they consumed were contaminated with NDMA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

490. As a result of the fraud, Plaintiff has suffered direct and consequential damages, and they seek recovery of those damages, and the creation of a fund to adequately finance the costs of medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all

necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following judgment:

1. Certifying this Action as a class action;

2. Appointing Plaintiff as Class Representative, and appointing undersigned counsel as Class Counsel to represent the Class;

3. A finding that Defendants are liable pursuant to each and every one of the above-enumerated causes of action;

4. Awarding appropriate preliminary and/or final injunctive relief;

5. Directing the Defendants to fund medical monitoring in an amount sufficient to fund necessary notice and medical care, including but not limited to examinations, tests, pathology, blood tests, evaluations, and treatment, as necessary and appropriate;

6. Payment to Plaintiff and other Class Members of compensatory damages necessary for their monitoring and care;

7. An award of attorneys' fees and costs;

8. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest; and

9. Such other and further relief as this Court may deem equitable and just.

JURY DEMAND

Plaintiffs respectfully request a trial by jury on all causes of action so triable.

Dated: October 1, 2020

Respectfully Submitted,

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